

REMARKS

Status of the Claims

Claims 18-22 and 24-35 are currently pending. Claims 1-17 and 23 have been canceled without prejudice or disclaimer of the subject matter claimed therein.

Claims 18-22, 25-33, and 35 have been amended. Representative support for the amendments to the claims can be found in each of the claims as originally submitted.

Applicants would like to thank the Examiner for vacating the restriction requirement and grouping claims 18-32 of Groups I-V as a single invention. Claims 22, 24, 25 and 30-32 read on the elected species. Claims 18-21 and 26-29 are withdrawn from consideration as being directed to non-elected species. Claims 33-35 are withdrawn from consideration as being directed to non-elected inventions.

Applicants point out that when a generic claim is found to be allowable, the restriction requirement as to the encompassed species must be withdrawn and the corresponding claims directed to the encompassed species should no longer be withdrawn from consideration. MPEP 809.02(c). It is Applicants' understanding that the Examiner intends to begin by searching the elected species and will continue searching until art is found or until a generic claim (directed to the molecular core ring structure) is found allowable. Applicants also point out that when a generic claim is found to be allowable, the withdrawn claims which depend from or include the limitations of the allowed claim must be rejoined and fully examined for patentability. MPEP 809.

Applicants respectfully point out that MPEP 821.04(b) requires that once a product claim, claims 22, 24, 25, or 30-32, is found allowable, withdrawn method claims, claims 33-35, which depend from or otherwise include all the limitations of the allowable product claim must be rejoined. Thus, once a claim directed to a product is found allowable, withdrawn method claims which depend from or otherwise include all the limitations of the allowed claim must be rejoined.

Priority

As requested, Applicants have updated the first paragraph of the specification to include a reference to PCT/GB05/00545, filed February 12, 2005, and to United Kingdom Applications

0403593.7, 04133863.4, and 04230379.7. However, Applicants respectfully point out that it is not necessary to amend the first sentence(s) of the specification to reference the international application number that was used to identify the application during international processing of the application by the international authorities prior to commencement of the national stage (see MPEP 1893.03(c)(III), page 1800-207 (8th Ed.)).

Claim Objection

Claims 22, 23, and 30-32 are objected to for informalities.

Applicants respectfully point out that in claim 22, HET-2 appears twice in the original definition of R⁴ because the first occurrence of HET-2 is as a substituent on (1-4C)alkyl and the second occurrence of HET-2 is as a moiety of R⁴. However, the definition of R⁴ has now been deleted, rendering the objection moot.

Rejections Under 35 U.S.C. § 112, First Paragraph

A. Claims 22-25 and 30-32 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for “prodrug” or “solvate” of Formula (I) and for methods of making or using the “prodrug” or “solvates”.

Applicants respectfully point out that they do not agree with this rejection. However, in the interest of advancing the prosecution of this application to allowance, Applicants have deleted the terms “solvate” and “pro-drug” from the claims.

Applicants respectfully point out that the term “solvate” is redundant and its removal does not affect the scope of these claims. In particular, Applicants maintain that any person skilled in this art would clearly be aware of what a solvate is, and that this art is sufficiently developed so that such skilled persons would have no difficulty in determining what solvent components of a solvate would be acceptable within the context of the claimed compounds and compositions. Nevertheless, it is apparent that whether a chemically defined compound is or is not in the form of a solvate is immaterial to the scope of these claims, and this superfluous recitation has therefore been removed by the above amendments, thus obviating this ground for rejection.

A solvate, in the pharmaceutical context as defined in Stedman’s Medical Dictionary (and similarly in the PDR Medical Dictionary), is simply “a nonaqueous solution or dispersoid in

which there is a noncovalent or easily reversible combination between solvent and solute, or dispersion means and disperse phase; when water is the solvent or dispersion medium, it is called a hydrate.” The solvent molecule of a solvate has been described as a species introduced into the crystal and no part of the organic host molecule is left out or replaced (see, *e.g.*, West, Solid State Chemistry at page 358). Thus, whether a chemically defined compound is or is not noncovalently associated with a solvent does not affect the scope of the claim to the compound, *per se*, any more than placing such compound in solution would remove the compound from the scope of such claim. Therefore, the alternative recitation of “a solvate ... thereof” is seen as being entirely superfluous, and neither expands nor contracts the scope of these claims. In other words, a claim to a novel compound *per se* encompasses such compound, regardless of its state of solvation or hydration, or its polymorphic form, and regardless of whether it is a racemic mixture or a resolved enantiomer.

Therefore, since the alternative recitation of “a solvate ... thereof” does not, and is not intended to, expand or limit the scope of these claims, all reference to the compounds alternatively being in the form of a “solvate” has been removed from the claims in order to expedite the prosecution of this application to allowance.

Accordingly, this rejection has been overcome by the cancellation of the terms “solvate” and “pro-drug” from all claims.

B. Claims 22, 23, and 30-32 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for R⁶ to be HET-4.

The definition for R⁶ has been amended to delete “HET-4”. Accordingly, the rejection is rendered moot.

C. Claims 22 and 30-32 are rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement for HET-2 and HET-3 comprising other substituents.

Claim 22 has been amended to delete HET-2. Claim 22 has also been amended to modify the definition of HET-3.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 22 and 30-32 are rejected under 35 U.S.C. § 112, second paragraph, as being

indefinite.

The Office Action alleges that the term “optionally substituted” recited in the definition of HET-2 is unclear. The substituent “HET-2” and its definition have been deleted from claim 22.

The Office Action alleges that R^4 , R^5 , R^7 , and HET-2 are not present in the definition of the substituents or in Formula (I). These substituents have been deleted from claim 22.

The Office Action alleges that the term “optionally substituted” in the definitions of HET-2 and HET-3 renders the claims unclear. Applicants do not agree with the rejection because the term “optionally substituted” means that it is either substituted or unsubstituted.. However, “HET-2” and its definition have been deleted from the claim, and the definition of “HET-3” has been amended to no longer recite “optionally substituted”.

Therefore, the claims are definite.

Rejection Under 35 U.S.C. § 103(a)

Claims 22-25 and 30-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 03015774 (Boyd).

As stated in the Office Action, Boyd does not disclose the claimed compounds because Boyd only discloses a benzyloxy substituent linked to the central phenyl ring of the generic benzamide formula. In contrast, the present claims are directed to a selected set of compounds in which the central phenyl is substituted in the 3-position by a mandatory methoxy(1-methyl)ethoxy group and in the 5-position by a mandatory phenoxy group that must be para-substituted by a HET3-CO or HET3-SO₂.

Moreover, the Examiner has not pointed to anything in the art that would suggest that it would be obvious to combine the methoxy(1-methyl)ethoxy group in combination with a phenoxy group that must be para-substituted by a HET3-CO- or HET3-SO₂ group on a central phenyl ring of a benzamide compound. Thus, there is no reason to modify the compounds disclosed in the cited reference to obtain the selected compounds of the present invention with reasonable expectation of success. Accordingly, the cited reference does not render the claimed invention obvious.

Applicants respectfully point out that in *In re Baird*, the court held that a disclosure of a generic formula that may encompass a claimed compound does not, without more render a

specific compound obvious. *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994). In *Baird*, the court found that a patent disclosing a generic diphenol formula encompasses various different diphenols in addition to the claimed bisphenol, did not render the claimed bisphenol obvious because the patent does not provide specific variables for picking the specific bisphenol. Similar to the facts in *In re Baird*, the cited reference, Boyd, teaches a generic benzamide formula but does not teach specifically selecting for compounds having the central phenyl ring substituted in the 5-position with methoxy(1-methyl)ethoxy group in combination with a phenoxy group that must be para-substituted by a HET3-CO or HET3-SO₂ group. Thus, Boyd does not render the claimed invention obvious.

Obviousness Double Patenting

A. Claims 22, 23, and 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22 and 30 of copending Application 11/665,222.

Application 11/665,222 has been abandoned. Thus, this rejection has been rendered moot.

B. Claims 22, 23, and 30-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22 and 30 of copending Application 11/665,163.

Applicants respectfully point out that this is a provisional rejection between two copending applications. MPEP 804 (I)(B)(1) (page 800-17) states,

If the “provisional” nonstatutory obviousness-type double patenting rejections are the only rejections remaining in those applications, the examiner should withdraw the obviousness-type double patenting rejection in the earlier filed application, thereby permitting that application to issue without need of a terminal disclaimer.

The present application is the earlier filed application. Thus, if this is the remaining rejection in the present application, Applicants respectfully request withdrawal of this rejection in accordance with MPEP 804 (I)(B)(1).

U.S. Patents and Pending U.S. Applications

Applicants respectfully provide the status of U.S. patents and pending U.S. applications with the same assignee that may be considered to be technically related for the Examiner's

consideration.

Application No.	Status
10/482,264	Patent 7,199,140
11/544,946	Abandoned
12/400,063	Pending; Preexam Processing
10/534,651	Patent 7,230,108
10/534,650	Pending; Response to Non Final Action Filed
10/482,572	Abandoned
11/634,966	Abandoned
10/486,496	Patent 7,390,908
12/024,561	Patent 7,524,957
12/363,899	Pending; Ready for Examination
10/578,021	Abandoned
10/579,552	Pending; Ready for Examination
10/579,337	Abandoned
10/579,782	Pending; Ready for Examination
10/588,315	Pending; Non Final Action Mailed
11/628,448	Pending; Response to Non Final Action Filed
12/336,170	Pending; Ready for Examination
11/665,247	Pending; Non Final Action Mailed
11/665,163	Pending; Ready for Examination
11/665,222	Pending; Non Final Action Mailed
11/876,370	Pending; Ready for Examination
11/913,219	Pending; Preexam Processing
11/913,114	Pending; Ready for Examination
11/924,888	Pending; Response to Non Final Action Filed
11/962,838	Pending; Response to Non Final Action Filed
11/995,079	Pending; Ready for Examination
11/995,077	Notice of Allowance Mailed
12/202,800	Pending; Non Final Action Mailed
12/203,324	Pending; Ready for Examination
12/256,254	Pending; Ready for Examination
11/995,079	Pending; Ready for Examination

Application No.	Status
12/063,252	Pending; Preexam Processing
12/066,967	Pending; Preexam Processing
12/095,101	Pending; Ready for Examination
12/520,223	Pending; Preexam Processing

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request entry of the amendments, reconsideration, and the timely allowance of the pending claims. A favorable action is awaited. Should an interview be helpful to further prosecution of this application, the Examiner is invited to telephone the undersigned.

If there are any fees due in connection with the filing of this Preliminary Amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: **June 29, 2009**
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